Updated COVID-19 Treatment Guidelines Panel's Statement on the Prioritization of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment or Prevention of SARS-CoV-2 Infection When There Are Logistical or Supply Constraints

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The COVID-19 Treatment Guidelines Panel (the Panel) has recommended the use of anti-SARS-CoV-2 monoclonal antibodies (mAbs) for the treatment of mild to moderate COVID-19 and for post-exposure prophylaxis (PEP) of SARS-CoV-2 infection in individuals who are at high risk for progression to severe COVID-19, as outlined in the Food and Drug Administration Emergency Use Authorizations (EUAs) issued for the anti-SARS-CoV-2 mAbs. See Therapeutic Management of Nonhospitalized Adults With COVID-19 and the Panel's statements on the EUAs for bamlanivimab plus etesevimab and casirivimab plus imdevimab as PEP for SARS-CoV-2 infection for recommendation ratings and more detailed information.

The anti-SARS-CoV-2 mAbs are of greatest benefit as treatment or PEP for people who have risk factors for progression to severe COVID-19. Among individuals at high risk of progressing to severe COVID-19, the risks are lower for those who have been fully vaccinated and are immunocompetent than for those who are either not fully vaccinated or fully vaccinated but not expected to mount an adequate immune response to the vaccine.

The purpose of this statement is to provide guidance on which individuals might receive the greatest benefit from anti-SARS-CoV-2 mAb therapy when logistical or supply constraints make it impossible to offer the therapy to all eligible patients, and triage becomes necessary. **Only when it becomes necessary to triage the use of the anti-SARS-CoV-2 mAbs**, the Panel suggests:

- Prioritizing the treatment of COVID-19 over PEP of SARS-CoV-2 infection; and
- Prioritizing anti-SARS-CoV-2 mAb therapy for unvaccinated or incompletely vaccinated individuals and vaccinated individuals who are not expected to mount an adequate immune response (e.g., individuals who are immunocompromised or on immunosuppressive medications or individuals aged \geq 65 years).

Providers should use their clinical judgment when prioritizing the use of anti-SARS-CoV-2 mAbs for treatment or PEP in a specific situation. The availability and distribution of authorized anti-SARS-CoV-2 mAbs should be monitored to ensure that access to the products is equitable.

Identifying Patients at Highest Risk of Progression to Severe COVID-19

When logistical or supply constraints limit the availability of anti-SARS-CoV-2 mAbs, the Panel recommends that, in addition to the prioritization strategies listed above, clinicians consider prioritizing their use for patients at highest risk of clinical progression. The <u>Centers for Disease Control and Prevention (CDC) website</u> provides a list of risk factors for severe illness from COVID-19. Some of the most important risk factors include (listed alphabetically) age (risk increases with each decade after age 50),¹ cancer, cardiovascular disease, chronic kidney disease, chronic lung disease, diabetes, immunocompromising conditions or receipt of immunosuppressive medications, obesity (body mass index ≥30), pregnancy, and sickle cell disease. For a complete list of risk factors, including information on the relative risk of severe disease, see the <u>CDC webpage Underlying Medical Conditions Associated with High Risk for Severe COVID-19</u>. Of note, the likelihood of developing severe COVID-19

increases when a person has multiple comorbidities.²

Although the data on risk factors for severe COVID-19 in children are limited, there is substantial overlap between risk factors in children and those identified in adults, as listed above. Children with obesity, moderate to severe immunosuppression, or those with complex chronic disease and medical complexity with respiratory technology dependence are at substantially increased risk of severe disease.³

The FDA EUAs provide a broad list of medical conditions or other factors as criteria for use of anti-SARS-CoV-2 mAbs as treatment or PEP. See the <u>individual EUAs</u> for the full list of these medical conditions and other factors.

References

- 1. Centers for Disease Control and Prevention. COVID-19 risks and vaccine information for older adults. 2021. Available at: https://www.cdc.gov/aging/covid19/covid19-older-adults.html. Accessed October 5, 2021.
- 2. Rosenthal N, Cao Z, Gundrum J, Sianis J, Safo S. Risk factors associated with in-hospital mortality in a US national sample of patients with COVID-19. *JAMA Netw Open*. 2020;3(12):e2029058. Available at: https://www.ncbi.nlm.nih.gov/pubmed/33301018.
- 3. Kompaniyets L, Agathis NT, Nelson JM, et al. Underlying medical conditions associated with severe COVID-19 illness among children. *JAMA Netw Open*. 2021;4(6):e2111182. Available at: https://www.ncbi.nlm.nih.gov/pubmed/34097050.